

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

*County of Summit, Ohio, et al. v. Purdue
Pharma L.P., et al.*

Case No. 1:18-OP-45090

*The County of Cuyahoga v. Purdue Pharma
L.P., et al.*

Case No. 17-OP-45004

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**MANUFACTURER DEFENDANTS' REPLY BRIEF IN SUPPORT OF MOTION FOR
SUMMARY JUDGMENT ON PLAINTIFFS' PUBLIC NUISANCE CLAIMS**

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I. Plaintiffs' Common Law Absolute Public Nuisance Claims Fail

A. Plaintiffs Cannot Show Proximate Cause

Plaintiffs continue to assert that the “public nuisance” for which they seek to hold Manufacturer Defendants liable is the “opioid crisis,” which they now further describe in their opposition papers as an “epidemic of opioid availability and use.” Opp’n at 1. This ill-defined and amorphous description of the public nuisance highlights why Plaintiffs’ claims fail.

Prescription opioid “availability” and “use” are not inherently harmful; indeed, these medications play a critical beneficial role in the health and lives of many patients.¹ Ohio law is clear that “[w]hat the law sanctions cannot be held to be a public nuisance.” *Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1143 (Ohio 2002) (citation omitted). Plaintiffs have now confirmed that the scope of their nuisance claims includes “availability and use” of FDA-approved, legal medications prescribed by doctors. See *City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 615 F.3d 496, 505 n.6 (6th Cir. 2010) (“[T]here is at least one other critical difference between this case and *Beretta*. . . . *Beretta* accused the defendants of [creating] an *illegal* market for guns, whereas, here, the Defendants allegedly financed a *legal* subprime mortgage market.”).

Plaintiffs’ “absolute public nuisance” claims cannot survive based merely on evidence that Manufacturer Defendants made prescription opioids available or that they were used. Even assuming something as multifaceted as the “opioid crisis” could ever be a public nuisance, to maintain their “public nuisance” claim against a particular Manufacturer Defendant, Plaintiffs would need to show that intentionally *wrongful* conduct by that Manufacturer Defendant caused

¹ “Tragically, we know that for some patients, loss of quality of life due to crushing pain has resulted in increased thoughts of or actual suicide. This is unacceptable. Reflecting this, even as we seek to curb overprescribing of opioids, *we also must make sure that patients with a true medical need for these drugs can access these therapies.*” July 09, 2018, Statement by FDA Commissioner Scott Gottlieb, M.D. (On Balancing Access to Appropriate Treatment for Patients with Chronic and End-of-life Pain with Need to Take Steps to Stem Misuse and Abuse of Opioids) (emphasis added), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-balancing-access-appropriate-treatment-patients-chronic>

improper “opioid availability” resulting in *harmful* “use” to such a degree as to constitute a “significant interference with the public health.” Restatement (Second) of Torts § 821B(2)(a).² Plaintiffs do not have evidence of this causal chain for any Manufacturer Defendant, let alone each of them, and nothing in their opposition brief changes that fact.

The recent Sixth Circuit decision in *City of Cincinnati v. Deutsche Bank*, 863 F.3d 474 (6th Cir. 2017), provides the relevant framework by which Plaintiffs’ claims must be evaluated, and shows why those claims fail. There, the defendant bank was the owner of foreclosed homes and had a “policy of violating local and state property regulations when the cost of compliance outweighed the value that could be recouped through the resale of a foreclosed property.” *Id.* at 476. The City alleged that this “policy” was wrongful conduct that resulted in a public nuisance because the neglect would cause a housing blight, leading to “lowered property tax revenues, increased police and fire expenses, and added other administrative costs.” *Id.* However, the City did not identify any example of a property that fell into neglect as a result of the policy. Instead, the City framed its case in the abstract, based on the theory that a policy of “selective non-compliance with health and safety codes will inevitably result in a public nuisance.” *Id.* at 479.

The Court rejected the City’s claims as too vague. Noting that the City only generally asserted that “[n]umerous known and unknown properties’ ‘were so deteriorated and dilapidated that they were declared public emergencies,’” the Court had no specifics, leaving it to wonder “[b]ut which properties?” *Id.* (emphasis added). Without details regarding “why a particular property owned by [defendant] endangers the public, we have no way of testing the plausibility of the nuisance allegations or assessing the proximity of” the alleged conduct to any harm. *Id.*

The City’s attempt to “sidestep these problems by wrapping the violations into one

² See also *State ex rel. R.T.G., Inc. v. State*, 780 N.E.2d 998, 1010 (Ohio 2002) (absolute public nuisance requires “intentional” creation of a nuisance or “an abnormally dangerous condition that cannot be maintained without injury”).

overarching nuisance: the ‘policy’” was insufficient. *Id.* As the Court noted, “bad intent alone does not a public nuisance make. Only where the intent (the ‘policy’) creates a nuisance can it be said to interfere with a public right.” *Id.* The Court recognized that the alleged wrongful conduct,

sometimes will create a nuisance. But sometimes it will not. *It all depends on the properties, the violations, and whether the combination produces unsafe or unsanitary conditions . . .* The City at a minimum must connect the policy to the existence of an actual nuisance.

Id. at 480 (emphasis added); *see also City of Cleveland*, 615 F.3d at 502-06 (affirming dismissal of nuisance claim for failure to sufficiently allege proximate cause).

Deutsche Bank illustrates the flaws in Plaintiffs’ approach. Rather than starting with a societal problem (there, urban blight; here, opioid abuse) and going in search of some antecedent, allegedly contributing cause, a plaintiff must begin with a defendant’s alleged wrongful conduct and consider the effects of that conduct. Liability can be found only where the plaintiff proves that the defendant’s actions proximately caused a public nuisance.

Here, Plaintiffs lack evidence that would causally connect any Manufacturer Defendant’s allegedly wrongful conduct to the creation of the “opioid crisis.” Indeed, Plaintiffs have not provided evidence of even a single example of *wrongful* conduct by a Manufacturer Defendant that *caused* any harm, let alone evidence of wrongful conduct that caused the “opioid crisis.” Plaintiffs did not, for example, identify particular prescriptions written as a result of improper marketing by any Manufacturer Defendant, let alone connect those prescriptions to any harm to any resident or increased public service costs by Plaintiffs. *See* Mfrs. Causation Brief at 6-9 (Dkt. 1894-1). Nor have Plaintiffs identified instances in which any Manufacturer Defendant shipped a “suspicious” order that Plaintiffs say should have been stopped, let alone any such failures that resulted in actual harm to any resident or that led to increased public services by Plaintiffs. *Id.* at 11-15; *see also* Mfrs. Opp’n to Partial MSJ re CSA Duties at 3-5 (Dkt. 2181).

This lack of evidence cannot be overcome by pointing to purported “aggregate” data. Plaintiffs supposed “aggregate proof” does not meet their burden, because it does not show that any wrongful conduct caused any harm (much less a public nuisance). In fact, that aggregate analysis is incapable of isolating any *wrongful* conduct let alone measuring its effect. Rather, Plaintiffs’ experts attempted to measure the aggregate effect of *all* prescription opioid promotion -- lawful or unlawful -- on *all* prescription opioid sales nationwide. *See* Mfrs. Causation Brief at 7-8 (Dkt. 1894-1). There is no way for a fact-finder to determine, based on any of Plaintiffs’ analyses, for example, which doctors, if any, were actually misled by Manufacturer Defendants’ purported fraudulent marketing and, as a result of that marketing (as opposed to other factors), wrote medically unnecessary or excess prescriptions.

Plaintiffs’ insistence on defining the public nuisance as the “opioid crisis” has no precedent in the law and is divorced from principles of causation. A defendant’s conduct is the legal cause only if the plaintiff can prove that the “conduct is a substantial factor in bringing about *the harm*.” Restatement (Second) Torts § 431 (emphasis added). A defendant’s conduct is “not a substantial factor in bringing about harm to another if *the harm* would have been sustained” in the absence of the defendant’s conduct.³ *Id.* § 432(1) (emphasis added); *see also Springsteel v. Jones & Laughlin Steel Corp.*, 192 N.E.2d 81, 87 (Ohio Ct. App. 1963) (recognizing import of Section 432(1)). The “harm” here as Plaintiffs define it is the all-encompassing “opioid crisis,” and Plaintiffs have not even considered whether (let alone adduced evidence that) each Defendant’s alleged wrongful conduct caused the “opioid crisis,” and that the crisis would not exist in the absence of that conduct. Indeed, Plaintiffs expressly disclaim that they have made any attempt to do this kind of analysis.

³ The only exception to this rule is where there is concurrent conduct by more than one actor, each of whose conduct is independently sufficient to cause “the harm.” Restatement (Second) Torts § 432(2). But in that situation, there needs to be evidence that each actor’s conduct “itself is sufficient to bring about *the harm*.” *Id.* (emphasis added). Plaintiffs have no such evidence for each Manufacturer, as discussed herein.

Plaintiffs' chief causation expert (Professor Rosenthal) includes in her report a table that she labels "Aggregate Percentage Harm Excluding Individual Defendants From Litigation," which on its face purports to reflect the amount of "harm" Professor Rosenthal would attribute to each Manufacturer Defendant. *See* Rosenthal Rpt. at 52, Table 3 (Dkt. 1999-22). Professor Rosenthal's opinions suffer from many independent fundamental flaws. *See* Mem. in Supp. of Mot. to Exclude Rosenthal Opinions (Dkt. 1913-1). Among those many flaws, her Table 3 does *not* in fact reflect the amount of "harm" attributable to each Manufacturer Defendant. The table only attempts to calculate the contribution to the alleged "harm" by each Manufacturer Defendant assuming that *all* detailing visits by a Manufacturer Defendant were "wrongful." Rosenthal admits this is not a valid assumption. *See* Rosenthal Tr. 153:24–154:5 (Dkt. 1984-4). In other words, even Professor Rosenthal recognizes that her methods do not provide evidence of the degree to which any Manufacturer Defendant's allegedly wrongful conduct caused "harm." *See also* Rosenthal Tr. 752:21-23 (Dkt. 1984-5) (conceding that her "assignment was to estimate the impact of the alleged misconduct and to quantify that *in aggregate*") (emphasis added); Rosenthal Tr. 164:4-9 (Dkt. 1984-4) (her models are "not designed to assign liability to individual manufacturers"). Plaintiffs' other experts also do not attempt to show the impact of any particular defendant's alleged wrongful conduct. Mfrs. Causation Brief at 16-19 (Dkt. 1894-1); *see also* Cutler Tr. 68:12-13 (Dkt. 1976-9) (acknowledging that he has "not done anything with respect to any specific defendant"). Similarly, Plaintiffs have provided no evidence about the relative impact of any Manufacturer Defendant on the "opioid crisis." As a result, there is no evidentiary basis for the contention that any one Manufacturer Defendant's allegedly wrongful conduct changed the "character and extent" of the "opioid crisis." *See* Restatement (Second) Torts § 432, cmt. *a*.

Plaintiffs' theory, if accepted, would turn public nuisance law on its head, and would set a

dangerous precedent. For example, a trier of fact could be asked to determine that “obesity” is a “public nuisance” in the abstract. Using that finding, a collection of soft drink manufacturers or fast food companies could be held liable for “abating” it because their collective marketing -- regardless of content or individual conduct -- increased the consumption of sugary or fatty foods. This is not the law in Ohio or anywhere else in America. Plaintiffs cannot simply presume causation because Manufacturers marketed lawful prescription opioids, and opioid-related problems exist. Plaintiffs must show that the *false* marketing of *each* Manufacturer Defendant was a substantial factor in creating a public nuisance. They have not even attempted to do so.

B. Plaintiffs Have No Evidence That The Manufacturer Defendants Intended To Create A Public Nuisance

Plaintiffs acknowledge the evidentiary bar they face for their public nuisance claim is high. Opp’n Mot. at 7. They must not only establish causation (which they fail to do as discussed above), but they also must prove Manufacturer Defendants “intended to bring about the conditions” of “the opioid epidemic.” *Nottke v. Norfolk S. Ry. Co.*, 264 F. Supp. 3d 859, 863-64 (N.D. Ohio 2017) (“intentional” means purposefully engaging in conduct where the “necessary consequence” of it is a nuisance). But the record is devoid of any evidence of such *intentional* conduct.

Plaintiffs point to a handful of company documents and expert opinions, all of which in effect say the same thing: the Manufacturer Defendants wanted to increase sales of their products. There is nothing wrong with marketing and selling an FDA-approved product. A company goal to sell a lawful product is a far cry from intent to cause the conditions of a public nuisance. The issue is whether there is any evidence of false marketing undertaken with the *intent* to bring about the harms of the alleged “opioid crisis.” There simply is no evidence anywhere in this record that Manufacturer Defendants *intended* the abuse, misuse, and addiction that Plaintiffs say constitute “the opioid crisis,” or that Manufacturer Defendants intended the harms caused by drug cartels’

expansion of the heroin and fentanyl black market in the Counties.

Plaintiffs also cite hearsay testimony from Dr. Russell Portenoy in a different case filed by the Oklahoma AG in which only three Manufacturer Defendants were parties. But Dr. Portenoy concedes he has no “personal knowledge of any particular marketing effort by any manufacturer,” and no “knowledge of any prescriber being influenced one way or the other by the inclusion of any of [his] articles in any marketing material.” Portenoy Tr. 287:1-5, 344:23-6 (Dkt. 1983-8). Nor do Plaintiffs cite any testimony from Dr. Portenoy about the intent of any Manufacturer, and, regardless, any of Dr. Portenoy’s personal “beliefs” about what any Manufacturer knew (or intended) has zero evidentiary value and cannot create a genuine issue of material fact.

As the Sixth Circuit has made clear, even “[k]nowledge” that the specific conduct at issue has caused a public nuisance is insufficient; it “does not equal intention.” *City of Cincinnati*, 863 F.3d at 478 (allegations that bank knew it created and maintained a public nuisance are insufficient). For this reason alone, summary judgment should be granted.

C. Plaintiffs Cannot Prove That Defendants Violated a “Public” Right

Plaintiffs are simply wrong that harm to a number of people can in itself constitutes a public nuisance. Opp’n at 4. The Restatement is clear: “Conduct does not become a public nuisance merely because it interferes with [rights] of a large number of persons.” Restatement (Second) Torts § 821B, cmt. g. A “public right” instead is one that “is common to *all* members of the general public” (*id.*), and, contrary to Plaintiffs’ assertions, merely invoking the term “public health” does not mean the rights at issue in a particular case are “public rights.”

Risks to public health that can impact the public in an undifferentiated way -- for instance, “the threat of communication of smallpox,” “keeping diseased animals,” or “maintenance of a pond breeding malarial mosquitoes” -- are examples in which the rights at issue are indeed “public.” *See id.* § 821B, cmt b, g. Each example cited in the Restatement by definition involves

an interference with a “public right” because any member of the public who is exercising the right to be present in that public locale, or to travel through it, encounters the health risk.

Addiction, even when suffered by a large number of people, is not like these examples. Patients do not become addicted by virtue of entering into a public space. If the prevalence of a non-communicable disease in itself were a public nuisance, individualized health ailments like alcoholism, heart disease, obesity, and diabetes could all constitute a “public nuisance” merely because they impact large numbers of citizens. There is no precedent to support this sweeping expansion of public nuisance law in Ohio as suggested by Plaintiffs.

II. Plaintiffs’ Statutory Public Nuisance Claim Also Fails

In support of their statutory public nuisance claim, Plaintiffs assert that there is “undisputed evidence of the Manufacturer Defendants’ repeated violations of the CSA.” Opp’n at 13. As detailed in the Manufacturers’ Opposition to Plaintiffs’ MSJ re CSA Duties, Plaintiffs have it exactly backward. The undisputed evidence shows that Plaintiffs have failed to identify a single suspicious order shipped by a Manufacturer to any customer in the Plaintiff counties. Mfrs. Opp’n to Partial MSJ re CSA Duties at 3 (Dkt. 2181). There also is no evidence of a more general violation of a CSA duty by any Manufacturer Defendant. *Id.* at 3-12; *see also id.* at 12-56 (detailing each Manufacturer Defendants’ compliance with CSA). And, in any event, Plaintiffs make no attempt to show a causal connection between any CSA violation(s) and the entire “opioid crisis” they seek to hold Defendants responsible for abating.

Plaintiffs’ statutory public nuisance claim fails for this reason as well.⁴

⁴ Plaintiffs speculate that there may be violations of other (non-CSA) statutes or regulations that could form the basis of a statutory public nuisance claim. But, the only non-CSA statutes or regulations alleged in Plaintiffs’ complaints have no applicability to the claims against the Manufacturer Defendants. *E.g.*, Summit 3AC ¶ 988 (citing Ohio R.C. § 2925.02(A)(1) and (3), which do not apply to “manufacturers” whose conduct does not violate certain other Chapters, only one of which (Chapter R.C. § 3719) has any application to manufacturers and which governs issues not relevant here, such as record keeping (§§ 3719.07, .13, .27), required labels (§ 3719.08), and authorized possession of controlled substances (§ 3719.09)).

August 16, 2019

Respectfully submitted,

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⁵ Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and an Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this motion, and, thus, they do not waive and expressly preserve their personal jurisdiction challenges.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 16th day of August 2019, I caused to be electronically filed notice of the foregoing with the Clerk of Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF System pursuant to the timing and protocols set in place by the Court.

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